

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-19. (Canceled)

20. (Currently Amended) A hydrophilic controlled release solid oral formulation comprising a matrix comprising, as a substantially homogeneous admixture, pregelatinized starch, an active ingredient selected from 9-hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a stereochemically isomeric form thereof, and one or more viscous hydrophilic polymers, wherein the pregelatinized starch is present in an amount sufficient to enable the formulation to maintain a controlled release of the active ingredient in media of changing ionic strength.

21. (Previously presented) The controlled release solid oral formulation of claim 20, wherein said one or more hydrophilic polymers are selected from the group consisting of alkylcellulose, hydroxyalkylcellulose, hydroxyalkylalkylcellulose, carboxyalkylcellulose, alkali metal salts of carboxyalkylcellulose, natural, semi synthetic or synthetic polysaccharide, polyacrylic acid and salts thereof, polymethacrylic acid and the salts thereof, polyvinyl alcohol, polyvinylpyrrolidone, and polyalkylene oxides.

22. (Previously presented) The controlled release solid oral formulation of claim 20, wherein said one or more hydrophilic polymers are selected from the group consisting of hydroxypropyl cellulose and hydroxypropylmethylcellulose.

23. (Previously presented) The controlled release solid oral formulation of claim 22, wherein said hydroxypropylmethylcellulose has a viscosity in a range from about 3,500 mPa.s to about 100,000 mPa.s.

24. (Previously presented) The controlled release solid oral formulation of claim 22, wherein said hydroxypropylcellulose has a viscosity of less than about 1,500 mPa.s.

25. (Previously presented) The controlled release solid oral formulation of claim 20, wherein said one or more hydrophilic polymers are present in an amount from about 0.01 to about 80 % by weight.

26. (Previously presented) The controlled release solid oral formulation of claim 20, wherein at least two hydrophilic polymers are present in said formulation.

27. (Previously presented) The controlled release solid oral formulation of claim 26, wherein said at least two hydrophilic polymers are hydroxypropylcellulose and hydroxypropylmethylcellulose,

28. (Previously presented) The controlled release solid oral formulation of claim 27, wherein a ratio of said hydroxypropylcellulose to said hydroxypropylmethylcellulose ranges from 1:5 to 5:1.

29. Canceled.

30. (Previously presented) The controlled release solid oral formulation of claim 20, wherein said pregelatinized starch is present at about 0.01 - 15 % by weight.

31. Canceled.

32. (Previously presented) A method of providing controlled release of 9-hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a stereochemically isomeric form thereof in a subject, comprising administering the controlled release solid oral formulation of claim 20 to said subject.

33. (Currently amended) A method of preparing a controlled release solid oral formulation comprising a step of mixing 9-hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a stereochemically isomeric form thereof with pregelatinized starch and one or more hydrophilic polymers, to provide a substantially homogeneous admixture thereof.

34. Canceled.

35. (Previously presented) The controlled release solid oral formulation of claim 20, wherein the media of changing ionic strength is fluid within a gastrointestinal tract.

36. (Previously presented) The controlled release solid oral formulation of claim 30, wherein said pregelatinized starch is present at about 5% (w/w).

37. (Previously presented) The controlled release solid oral formulation of claim 30, wherein said pregelatinized starch is present at about 5% to about 15% (w/w).

38. (Currently amended) A hydrophilic controlled release solid oral formulation comprising a matrix comprising, as a substantially homogeneous admixture, pregelatinized starch, an active ingredient selected from 9-hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a stereochemically isomeric form thereof, and one or more viscous hydrophilic polymers, wherein the pregelatinized starch is present in an amount sufficient to prevent dose-dumping from said formulation along the gastrointestinal tract both in fasted as well as in fed conditions.

39. (Previously presented) The controlled release solid oral formulation according to any one of claims 20 to 28, 30, or 35 to 38 in the form of a tablet consisting essentially of an optional coating and a controlled release matrix comprising a substantially homogeneous admixture comprising said active ingredient, said one or more viscous hydrophilic polymers, and said pregelatinized starch.